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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,831	03/09/2006	Hans-Ulrich Petereit	267336US0PCT	8866
22850 7590 04/24/2009 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER WESTERBERG, NISSA M	
			ART UNIT	PAPER NUMBER
			1618	
			NOTIFICATION DATE	DELIVERY MODE
			04/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/532,831	Applicant(s) PETEREIT ET AL.	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 6, 8 - 11, 13 - 16 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 6, 8, 9, 13 - 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 2, 2009 has been entered.

Claim Objections

2. Claims 4 – 6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The outer coating polymers recited in claims 4 – 6 fall outside the scope of the outer coating polymer recited in amended claim 1, from which claims 4 – 6 depend.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 1 – 6, 8, 9 and 13 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulmius et al. (US 5,643,602) in view of Beckert et al. (WO 01/68058 with citations from the English equivalent US 2002/0192282). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 1, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that the art does not provide a reasonable expectation of the improved results obtained by the formulation specified in the claims in regards to the robust hypotonic/isotonic dissolution behavior. Even if the combination of the EUDRAGIT® NE polymer for the inner matrix taught by Ulmius with the EUDRAGIT® FS polymer for the outer matrix as taught by Beckert et al. was appropriate, the art would never expect the “hypotonic/isotonic” effect clearly demonstrated for the claimed invention. Something that is alleged to be inherent must necessarily be so and the evidence in the specification shows that compositions within the scope of Ulmius do not exhibit that ionic strength stability and even in view of WO 01/68767, the advantages of the claimed formulation were not predictable. It has been discovered that the inner methacrylate copolymer comprising at least 90% by weight of (meth)acrylate monomers having neutral radical, wherein the methacrylate copolymer has a minimum film-forming temperature not exceeding 30°C can provide the active ingredient without the aid of excipients such as plasticizers or release agents as is typically the case and it not at all suggested by Ulmius. Nothing in Ulmius provides the direction to select the methacrylate polymers from among all the possible monomers. There is not a reasonable expectation of success from the teachings of the cited art for

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the percentage of active substance release as defined in claims because the evidence shows that combinations within the scope of Ulmius results in compositions that fall outside the scope of claim 1. The rejection of Ulmius in view of Beckert was raised primarily because Ulmius only teaches glucocorticosteroid active ingredients and does described methacrylate type polymers for the outer coating, it does not alter the fact that the claims are not rendered obvious.

These arguments are not found persuasive. The purpose of the reference to WO 01/68767 is not understood by the Examiner as no mention or rejection over this piece of prior art has been made. The Examiner also wishes to repeat that Beckert et al. is cited not only for its teaching of other active ingredient types but also because it teaches EUDRAGIT® FS polymer as suitable for the outer coating (¶ [0087]). EUDRAGIT® FS meets the limitations present in claim 1, subitem c) for the composition of the outer coating.

Applicant argues that no expectation of success exists because no guidance for the production of a multilayered pharmaceutical dosage form that exhibits a “hypotonic/isotonic” dissolution profile is present in the cited prior art. In response to this argument, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Both Ulmius and Beckert et al. provide relatively limited lists of polymers which are suited for the inner and outer polymer layers of a multilayered pharmaceutical device. The person of ordinary skill would have a

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reasonable expectation of success that a dosage form with the various layers can be prepared. Each of the multilayered dosage forms so prepared inherently has a particular release profile for the active ingredient. Applicant has indicated that not all of the dosage forms prepared using combinations of inner and outer polymer layers disclosed within Ulmuis alone or with those polymers disclosed by Beckert et al. result in a dosage form that has a hypotonic/isotonic release profile. That applicant has recognized another advantage, namely a less than 10% different in the release of the active substance under hypotonic and isotonic medium, which would flow naturally from following the suggestion of the prior art to prepare multilayered dosage forms which a different combination of polymers for an inner and outer layer cannot be the basis for patentability when the prior art teaches the physical structure of dosage forms that provide that advantage. The fact that not all of the compositions disclosed by Ulmuis et al. and Beckert et al. do not possess the hypotonic/isotonic release profile is not relevant as the combination of references teaches a dosage form with an inner, coating such as EUDRAGIT® NE 30D and EUDRAGIT® FS as an outer coating, a dosage form which has the same active ingredient release profile under hypotonic and isotonic conditions.

Ulmuis et al. discloses that plasticizers and release agents are only optional ingredients with the film-forming polymers. Thus, one of ordinary skill in the reading, upon reading that these ingredients are merely optional and are not required components in the dosage form, would recognize that the film-forming polymer layers can be made and ingredients such as plasticizers and release agents can be omitted.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Examiner, Art Unit 1618

NMW

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